Executive Officer Notice:

Proposed regulatory amendments under the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act* to modernize submission requirements for "well-established drugs."

October 19, 2023

The Ministry of Health (ministry) is proposing regulatory amendments under the *Ontario Drug Benefit Act* (ODBA) and the *Drug Interchangeability and Dispensing Fee Act* (DIDFA) that, if approved, would modernize the submission requirements for manufacturers of "well-established" brand and generic drug products.

Well-established drugs are drug products that are not "new drugs" as defined in the Food and Drug Regulations made under the *Food and Drugs Act* (Canada). In other words, they are drug products containing substances that have been sold in Canada for sufficient time and in sufficient quantity to establish their safety and effectiveness.

Manufacturers of brand and generic drug products are required to make a submission to the ministry to have their products funded under the Ontario Drug Benefit (ODB) program. In the case of generic drug products, the submissions are also used to designate generic drug products as interchangeable with brand drug products. The requirements for making these submissions are set out in the regulations made under the ODBA and the DIDFA.

Currently, Ontario's submission requirements for brand and generic drugs are not fully aligned with Health Canada's requirements for approving well-established drugs for sale in Canada. This misalignment may prevent manufacturers of well-established drugs from having their products funded under the ODB program and/or designated as interchangeable in Ontario.

The proposed regulatory amendments, if approved, would reduce this burden by ensuring that Ontario's submission requirements are better aligned with Health Canada's requirements for well-established drugs. The proposed amendments would also improve Ontarians' access to publicly funded drugs under the ODB program and lower cost generic

drugs. Timely patient access to drugs will positively impact Ontarians, reducing the burden of illness and overall health care utilization.

Regulatory Registry Posting

A summary and draft of the proposed regulatory amendments are available on the Regulatory Registry website at:

Proposed regulatory amendments under the Ontario Drug Benefit Act and the Drug Interchangeability and Dispensing Fee Act to modernize submission requirements for manufacturers of "well-established drugs" (ontariocanada.com)

The final content of any regulatory amendments described in this notice are at the discretion of the Lieutenant Governor in Council ("LGIC") who may make the regulatory amendments with any changes that the LGIC considers appropriate.

Interested parties are invited to provide written comments on the proposed changes to the regulation as part of the review. The ministry will consider comments received on or before **December 3, 2023 at 11:59pm EST at midnight EST**. Please be advised that submissions received after this date may not be considered.

Please submit your written comments to:

Health Programs and Delivery Division
Ministry of Health
5700 Yonge Street, 3rd Floor
Toronto ON
M2M 4K5
Fax: 416-325-6647
E-mail: PublicDrugPrgrms.moh@ontario.ca

Statement about Comments

Unless requested and otherwise agreed to by the ministry, all materials or comments received from organizations in response to the notice will be considered public information and may be used and disclosed by the ministry as part of its review. The ministry may disclose materials or comments, or summaries of them, to other interested parties during and after the comment period.

An individual who makes a submission and who indicates an affiliation with an organization in his or her submission will be considered to have made his or her submission on behalf of the affiliated organization. The ministry will not disclose any personal information contained in a submission of an individual who does not specify an organizational affiliation in his or her submission without the individual's consent unless required by law. However, the ministry may use and disclose the content of the individual's submission to assist the ministry in its review. If you have any questions about the collection of this information, you can contact the ministry's Freedom of Information and Privacy Coordinator at (416) 327-7040.